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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/272,835	03/19/1999	FREDERIC J. DE SAUVAGE	P1268R1	6145

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/272,835	DE SAUVAGE ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *98-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *98-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/11/05 has been entered.

2. Applicant's arguments filed 1/11/05 have been fully considered but they are not persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 98-102 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility, for the reasons made of record in Paper NOs: 10 (mailed 10/27/00), 24 (mailed 7/24/02), 37 (mailed 10/01/03) & 20040325, and as follows.

Applicants argue on pages 3-15 of the response that "a prima facie of lack of utility has not been established", "[t]he application discloses [a] specific, substantial and credible utility", that "[t]he claimed nucleic acids have inherent utility that is specific and substantial", and cites

Brenner v. Manson, *Raytheon v. Roper*, *In re Oetiker*, *In re Langer*, *In re Jolles*, *In re Irons*, *In re Sichert*, *Parker v. Frilette*, *Cooper v. Goldfarb*, *Burroughs Wellcome Co v. Barr Laboratories, Inc.*, *Atlas Powder Co. v. Ireco Inc.*, and *Schering Corporation v. Geneva Pharmaceuticals, Inc.* Applicants then incorrectly assert that "the Examiner assumes that an 'orphan receptor' necessarily lacks utility", that "Applicants provide GFRα3 ligands" (see pg. 10 of the response), and that "Applicants in fact demonstrated binding of ligands to (chimeric) GFRα3 receptors" (see pg. 11 of the response). In contrast to Applicants' assertions, Applicants merely base utility on a laundry list of prophetic and unrelated utilities, which require "**ligand-induced** α-subunit receptor activation [after dimerization]", "**[l]igand-mediated** activation", and use of "**ligands to GFRα3**... for treatment of diseases or conditions of the peripheral nervous system" [emphasis added] (e.g., see pg. 6 of the response). However, each of these alleged generic utilities require knowledge of the "ligand" for this receptor, by definition, which the specification fails to define or "demonstrate". Therefore, in this particular case, because the ligand for GFRα3 is unknown in the art at the time of filing Applicants invention, and not specifically described within the instant specification, what biological activity the unknown ligand for this receptor actually possesses is required to establish a utility for this orphan receptor, based upon the specification's own disclosure. Lastly, it should be noted that "inherency" is an issue under 35 U.S.C. 102, and not an issue under 35 U.S.C. 101, and that Baloh's receptor (Dec., 1998; IDS Ref # 2) discussed on page 13 of the response is not the encoded polypeptide of SEQ ID NO: 17, as claimed; thereby, making Applicants' arguments moot concerning what utility their nucleic acid actually possesses after the claimed priority date of this application. Accordingly, the court in *Vas-Cath Inc. v. Mahurkar,* 19 USPQ2d 1111, 1117, still makes clear that "applicant must convey with

reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession *of the claimed invention* [emphasis added]", which the current specification clearly does not "specifically" describe in a definable and assayable way.

Therefore, as previously made of record, an invitation for others to discover the utility of Applicants' invention by merely providing a laundry list of prophetic and unrelated utilities does not address the issue as to what "specific" use, or "specific" and assayable function, the instant invention possesses. Nor does the general demonstration of "receptor dimerization" (i.e., a property of many different receptors), or the possibility of future ligand or "agonist antibody" screening, address this question of "specific" utility. Nor does a laundry list of prophetic disease states that may be treatable address the question of a "real world" use of the instant invention, in that not a single specific disease state is disclosed within the instant specification to be caused by a dysfunctional GFRα3 receptor, or is specifically disclosed to be "treatable" in a specific and definable assay. In other words, how a "GFR *family* of receptors" may, or may not, *generally* function does not address what the claimed unique "GFRα3" receptor molecules specifically do. Again, as previously made of record, the native ligand of GFRα3 was "unknown" at the time of filing the present invention, as stated the specification itself; thereby, preventing one of skill in the art to know what constitutes "*ligand*-induced activity" or "*ligand*-mediated activation", or know what "treatment of diseases or conditions" are reasonably possible using such an unknown and undescribed "ligand to GFRα3", by definition. Likewise, no specific cell type is described within the instant specification that expresses a *functional* GFRα3 receptor of SEQ ID NO: 17, if such "function" is later discovered, which then can be assayed. Moreover, no where on pages 28, 29, 18, 56, 57, Example 10, page 55, Figure 12, page 58, or pages 27-29 is any demonstration

of a "single" *specific* use described for the claimed nucleic acid; thereby, not reasonably satisfying the requirements under 35 U.S.C. 101.

As previously made of record, the instant situation is analogous to that decided by the courts in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. In particular, the court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "*a patent is not a hunting license*", *"[i]t is not a reward for the search, but compensation for its successful conclusion* [emphasis added]."

Therefore, because no known "specific" biological activity is described within the instant specification nor "specifically" associated with any nucleic acid that encodes the polypeptide of SEQ ID NO: 17, because the specification merely discloses on page 55 that "the human AGFRα3 does not bind any of these [GDNF family member] molecules (Figure 9C)", and that "AGFRα3 is thus an orphan receptor" that requires unknown and undescribed "ligand-induced... activation" or "ligand-mediated activation", the claimed polynucleotides have no specific nor substantial utility, because further experimentation is also necessary at the time of filing the

instant invention to attribute a function and "real world" utility to the claimed nucleic acid molecules; thereby, clearly establishing a *prima facie* case for a lack of utility for the instant invention.

5. Claims 98-102 also stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons made of record in Paper NOs: 10, 24, 37 & 20040325.

6. This is a RCE of applicant's earlier Application No. 09/272,835. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
March 28, 2005

ROBERT C. HAYES, PH.D.
PATENT EXAMINER